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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,904

07/10/2003

Laura T. Bortolin

0050.2060-001

1657

21005

7590

05/01/2006

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EXAMINER

BERTAGNA, ANGELA MARIE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,904

Applicant(s)

BORTOLIN ET AL.

Examiner

Angela Bertagna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 10-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/27/2004; 9/7/2004; 4/1/2005; 2/17/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-9 in the reply filed on March 9, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 10-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on March 9, 2006.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "34" and "96" have both been used to designate a porous support (see Figure 5, where reference character 96 refers to a porous support). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in

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the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Specifically, the abstract uses the phrase "means that include a magnetic substrate".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Pourahmadi et al. (US Patent No. 6,440,725 B1).

Pourahmadi discloses a nucleic acid purification cartridge (abstract and Figure 2).

With regard to claims 1 and 9, Pourahmadi teaches an apparatus comprising:

- (a) a porous support including an agent that deactivates a nucleic acid amplification inhibitor (column 6, lines 1-4; note that the filter may be designed to trap amplification inhibitors: column 12, lines 34-50)
- (b) a housing having an opening and defining an interior, where the interior is in fluid communication with the porous support (column 3, line 65 – column 4, line 7; where the “external instrument for receiving the cartridge” is the equivalent of the instantly claimed housing. Note that the instrument is in fluid communication with the cartridge that contains a porous support)
- (c) separating means that include a magnetic substrate (column 18, lines 40-50 where functionalized magnetic beads are taught; column 12, lines 30-31 teach streptavidin coating).

With regard to claim 2, the separating means of Pourahmadi comprises:

- (a) a vessel having an inlet at a first end and an outlet at a second end, distal to said first end (column 18, lines 40-50 teach a reservoir of magnetic beads in the cartridge; column 6, lines 8-17 teach that the capture area **122** of the cartridge is a microfluidic structure with an inlet and outlet; see also Figure 2)
- b) an ampoule contained within the vessel, said ampoule containing magnetic beads (column 18, lines 40-50)
- c) a valve at the second end of the vessel (see Figure 2 and column 6, line 67 – column 7, line 1)

d) a magnet at said valve (column 18, lines 45-52).

With regard to claim 3, Pourahmadi teaches the use of AC electromagnetic fields to cause the magnetic beads contained in a reservoir to “circulate within a small region of the cartridge to mix fluids within the cartridge” (column 18, lines 48-50). Since all fluids have some buffering capacity, this disclosure of Pourahmadi meets the instant limitation that the ampoule contains a buffer solution.

With regard to claims 4-5 and 7, Pourahmadi teaches that the valve is rotatable, whereby magnetic beads held at one end of the valve can be moved to a second end of the valve and thereby placed into contact with the porous support, and further, that the magnet is removable from the valve, whereby the magnetic beads can be attached to the magnet within the vessel while the valve is in one position, and while the valve is in a second position, the magnet can be removed and the magnetic beads released into contact with the porous support (column 18, lines 40-62). Also, note that since Pourahmadi states that this system allows the user to maintain complete fluid control, this inherently includes movement of the magnetic beads in an upward direction if desired.

With regard to claim 6, the cartridge of Pourahmadi includes a removable cap for sealing off the lysing chamber that is located at the first end of the interconnected vessel (column 32, lines 40-50 and Figure 16).

With regard to claim 8, the “external instrument” that is the equivalent of the claim housing may be detached from the cartridge (see Figure 3).

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6. Claim 1 is rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Dority (US Patent No. 6,374,684 B1).

Dority teaches a fluidic system for nucleic acid purification (see abstract and Figure 3).

With regard to claim 1, Dority teaches an apparatus comprising:

- (a) a porous support including an agent that deactivates a nucleic acid amplification inhibitor (column 1, line 64 – column 2, line 4; see also column 2, lines 33-39 where the filters trap amplification inhibitors such as proteins)
- (b) a housing having an opening and defining an interior, where the interior is in fluid communication with the porous support (column 1, line 64 – column 2, line 4; see also Figure 3, part number 12)
- (c) separating means that include a magnetic substrate (column 2, line 3; see also column 5, lines 32-35, where additional “active members” which include the magnetic separation matrix may be included).

Conclusion

No claims are currently allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Southgate et al. (US Patent No. 5,863,801) teach a nucleic acid separation device based on magnetic bead separation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is (571) 272-8291. The examiner can normally be reached on M-F 7:30-5 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Angela Bertagna
Patent Examiner
Art Unit 1637

amb



JEFFREY FREDMAN
PRIMARY EXAMINER

